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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO
10/600,070	06/20/2003	Katherine W. Osteryoung	MSU-08153	5938
7590 03/03/2006		EXAMINER		
J. Mitchell Jones			KUBELIK, ANNE R	
MEDLEN & C Suite 350	CARROLL, LLP	ART UNIT	PAPER NUMBER	
101 Howard Street			1638	
San Francisco,	CA 94105	DATE MAILED: 03/03/2006		

Please find below and/or attached an Office communication concerning this application or proceeding.

· · · · · · · · · · · · · · · · · · ·		Application No.	Applicant(s)			
Office Action Summary		10/600,070	OSTERYOUNG ET AL.			
		Examiner	Art Unit			
		Anne R. Kubelik	1638			
The MAILING DATE of this con Period for Reply	nmunication appe	ars on the cover sheet t	with the correspondence address			
A SHORTENED STATUTORY PERIOD WHICHEVER IS LONGER, FROM T  - Extensions of time may be available under the proafter SIX (6) MONTHS from the mailing date of thi  - If NO period for reply is specified above, the maxin  - Failure to reply within the set or extended period for Any reply received by the Office later than three meanned patent term adjustment. See 37 CFR 1.70	HE MAILING DA: visions of 37 CFR 1.136 s communication. num statutory period will or reply will, by statute, conths after the mailing of	TE OF THIS COMMUN (a). In no event, however, may a l apply and will expire SIX (6) MO ause the application to become	IICATION. a repty be timely filed  DNTHS from the mailing date of this communication.  ABANDONED (35 U.S.C. § 133).			
Status						
1) Responsive to communication(	s) filed on 23 Ma	y 2005 and 17 August	2005.			
2a) ☐ This action is FINAL.						
3) Since this application is in cond	) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is					
closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11, 453 O.G. 213.						
Disposition of Claims						
4)⊠ Claim(s) <u>1,4-6,8-17 and 22</u> is/a	re pending in the	application				
4a) Of the above claim(s) is/are withdrawn from consideration.						
5) Claim(s) is/are allowed.						
6)⊠ Claim(s) <u>1,4-6,8-17 and 22</u> is/are rejected.						
7) Claim(s) is/are objected to.						
8) Claim(s) are subject to r	estriction and/or	election requirement.				
Application Papers						
9)⊠ The specification is objected to	by the Examiner					
10)⊠ The drawing(s) filed on <u>24 February 2004</u> is/are: a) accepted or b)⊠ objected to by the Examiner.						
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).						
			g(s) is objected to. See 37 CFR 1.121(d).			
	11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.					
Priority under 35 U.S.C. § 119	·					
<u> </u>	Join for foreign n	rierity under 25 H.S.C.	\$ 110(a) (d) a= (5)			
12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f). a) All b) Some * c) None of:						
1. Certified copies of the priority documents have been received.						
Certified copies of the priority documents have been received.      Certified copies of the priority documents have been received in Application No						
3. Copies of the certified copies of the priority documents have been received in Application No						
application from the International Bureau (PCT Rule 17.2(a)).						
* See the attached detailed Office action for a list of the certified copies not received.						
		· · ·				
Attachment(s)						
1) Notice of References Cited (PTO-892)			Summary (PTO-413)			
2) Notice of Draftsperson's Patent Drawing Review (PTO-948)  3) Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  Paper No(s)/Mail Date.  5) Notice of Informal Patent Application (PTO-152)						
Paper No(s)/Mail Date	++3 01 L10/2R/08)	6) ⊠ Other: <u>se</u>				
U.S. Patent and Trademark Office PTOL-326 (Rev. 7-05)	Office Acti	on Summary	Part of Paper No./Mail Date 206			

### **DETAILED ACTION**

1. Applicant's election without traverse of Group I (claims 1, 4-6, 8-17 and 22) in the reply filed on 23 May 2005 is acknowledged. Applicant also elects SEQ ID NO:3 and states that the remaining sequences will be examined if the elected sequences is found allowable. This is not true; the requirement to select a single sequence specifically states that this is a restriction, not an election of species. Furthermore, claim 1 is not treated as a linking claim for the sequences, as all the sequences are recited in the alternative.

SEQ IS NO:3 is the genomic sequence encoding SEQ ID NO:2; SEQ ID NO:1 is the cDNA encoding SEQ ID NO:2. The claims will be examined to the extent they are drawn to nucleic acids encoding SEQ ID NO:2, and the restriction between SEQ ID NO:1 and 3 is withdrawn.

Applicant is required to cancel nonelected sequences or take other appropriate action (37 CFR 1.144). See MPEP § 821.01.

The requirement is still deemed proper and is therefore made FINAL.

2. The drawings filed 24 February 2004 are objected to for the following reasons:

Figures 1-2, 6-24 and 26-27 are objected to because tables and sequence listings that are included in the specification are, except for applications filed under 35 U.S.C. 371, are not permitted to be included in the drawings. See 37 CFR 1.83 (a).

Figures 5, 8-10, 12, 17, 20, 24, 26 are objected to because partial figures intended to form one complete view, on one or several sheets, must be identified by the same number followed by a capital letter. See 37 CFR 1.84 (u).

Application/Control Number: 10/600,070

Art Unit: 1638

Figures 4-5 and 25 are objected to because the letters in the black boxes cannot be made out.

Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the examiner does not accept the changes, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

3. The disclosure is objected to for the following reasons:

It contains embedded hyperlinks and/or other form of browser-executable code. See pg 40, line 29; pg 41, lines 1 and 3; pg 60, line 20; pg 86, line 26; pg 87, lines 4, 6, 9, 11, 13, 15, 16 and 19-30; pg 88, lines 2-3, 7-10, 14 and 17; pg 94, lines 3, 6-8; pg 103, lines 5 and 8; and pg 11, line 4. Applicant is required to delete the embedded hyperlinks and/or other form of browser-executable code. See MPEP § 608.01.

The Brief Description of Figure 5 is objected to because the symbols are missing.

4. It is suggested that Table 3 be amended to include the SEQ ID NOs: for each sequence.

#### Claim Objections

5. Applicant is advised that should claims 8-12 be found allowable, claims 13-17 will be objected to under 37 CFR 1.75 as being a substantial duplicate thereof. When two claims in an

application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k).

# Claim Rejections - 35 USC § 112

- 6. The following is a quotation of the first paragraph of 35 U.S.C. 112:
  - The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.
- 7. Claims 1, 4-6 and 8-17 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a nucleic acid encoding SEQ ID NO:2, does not reasonably provide enablement for Ftn2 genes or to nucleic acids that hybridize to an Ftn2 gene that encodes SEQ ID NO:2, vectors comprising it and cells, plants and seeds transformed with it. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.

The claims are broadly drawn to Ftn2 genes or to nucleic acids that hybridize to an Ftn2 gene that encodes SEQ ID NO:2, vectors comprising it and cells, plants and seeds transformed with it.

The instant specification, however, only provides guidance for isolation of Ftn2 from *Synechococcus* and identification of putative cynaobacterial homologs (examples 4 and 5), which has 17% identity to an unknown protein (SEQ ID NO:2, encoded by the genomic sequence SEQ

ID NO:3 and cDNA SEQ ID NO:2) in *Arabidopsis*; mapping the *arc6* mutation in *Arabidopsis* to show that it and the unknown protein map to chromosome 5 (example 2); rescuing the *arc6* mutation by SEQ ID NO:1 (example 2); analysis of the mutant to show that FtsZ rings and filaments are disrupted (example 2); identification of potential Ftn2 homologues from various database sequences (example 3); identification of arc5 (examples 6) and Fzo-like (example 7) genes from *Arabidopsis*. The specification teaches that Ftn2 does not have a proper DnaJ domain or a complete myb domain, but appears to have a chloroplast targeting sequence and three putative transmembrane helices (pg 90-91).

The instant specification fails to teach how to make nucleic acids that hybridize to a nucleic acid that encodes SEQ ID NO:2, wherein the nucleic acids encode AtFtn2 proteins.

The instant specification fails to provide guidance for which amino acids of SEQ ID NO:2 can be altered and to which other amino acids, and which amino acids must not be changed, to maintain Ftn2 activity of the encoded protein. The specification also fails to provide guidance for which amino acids can be deleted and which regions of the protein can tolerate insertions and still produce a functional enzyme.

Making "conservative" substitutions (e.g., substituting one polar amino acid for another, or one acidic one for another) does not produce predictable results. Lazar et al (1988, Mol. Cell. Biol. 8:1247-1252) showed that the "conservative" substitution of glutamic acid for aspartic acid at position 47 reduced biological function of transforming growth factor alpha while "nonconservative" substitutions with alanine or asparagine had no effect (abstract). Similarly, Hill et al (1998, Biochem. Biophys. Res. Comm. 244:573-577) teach that when three histidines

that are maintained in ADP-glucose pyrophosphorylase across several species are substituted with the "nonconservative" amino acid glutamine, there is little effect on enzyme activity, while the substitution of one of those histidines with the "conservative" amino acid arginine drastically reduced enzyme activity (see Table 1). The nucleic acids encoding all these mutated proteins, however, would hybridize under high stringency to the nucleic acids encoding the original protein.

The only assay for FTN2 function is complementation of the arc6 mutation with a nucleic acid encoding SEQ ID NO:2 (exmaple2). It is not clear that other nucleic acids that hybridize to any nucleic acid that encodes SEQ ID NOL:2 would be able to complement this mutant, given the importance of individual amino acids in portion-protein interactions.

Given the claim breath, unpredictability, and lack of guidance as discussed above, undue experimentation would have been required by one skilled in the art to develop and evaluate Ftn2-encoding nucleic acids that hybridize to a nucleic acid that encodes SEQ ID NO:2. Making all possible single amino acid substitutions in an 801 amino acid long protein like that encoded by SEQ ID NO:1 and 3 would require making and analyzing 19<sup>801</sup> nucleic acids; these proteins would have 99.8% identity to SEQ ID NO:2. Because nucleic acids that hybridize to a nucleic acid that encodes SEQ ID NO:2 would encode proteins with many amino acid substitutions, many more than 19<sup>801</sup> nucleic acids would need to be made and analyzed. Guo et al (2004, Proc. Natl. Acad. Sci. USA 101: 9205-9210) teach that while proteins are fairly tolerant to mutations resulting in single amino acid changes, increasing the number of substitutions additively increases the probability that the protein will be inactivated (pg 9209, right column, paragraph

2). Thus, making and analyzing proteins with many amino acid substitutions that also have Ftn2 activity would require undue experimentation.

The specification does not teach how to use plants in which Ftn2 is overexpressed. The phenotype of such plants is not taught; thus one of skill in the art would not know how to use them.

As the specification does not describe the transformation of any plant with an Ftn2 gene or to a nucleic acid that hybridizes to an Ftn2 gene that encodes SEQ ID NO:2, undue trial and error experimentation would be required to screen through the myriad of nucleic acids encompassed by the claims and plants transformed therewith, to identify those with an unspecified phenotype.

Given the claim breath, unpredictability in the art, undue experimentation, and lack of guidance in the specification as discussed above, the instant invention is not enabled throughout the full scope of the claims.

8. Claims 1, 4-6 and 8-17 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter that was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The essential feature of the claims is an Ftn2 gene or a nucleic acid that hybridizes to an Ftn2 gene that encodes SEQ ID NO:2. As the protein and its activity are novel, there is no welldeveloped field of prior art.

The specification describes FTN2 function as a protein that when its level are decreased leads to incomplete or no division of a prokaryote or plastid, resulting in long filamentous cells in cyanobacteria and single or few very large chloroplasts in plants (pg 15, lines 1-10).

The specification describes Ftn2 proteins as having a DnaJ-like domain at its N-terminal half, but that this domain is missing the essential central HPD motif (pg 60, lines 7-10; pg 90, lines 12-17). Otrer motifs are described (pg 60, lines 11-20; pg 90, lines 17-27; Table 7), but such motifs are not present in every protein indicated to be an Ftn2 homolog.

There is no description of the structure required for the recited function, and no description of the necessary and sufficient structural elements of a protein with Ftn2 function.

Furthermore, the specification describes no complete Ftn2 gene, with all its 5' and 3' regulatory elements.

The only species described in the specification is SEQ ID NOs:3 and 4, which encode SEQ ID NOs:2 and 5, respectively; these sequences do not include the complete regulatory elements of the genes. The putative homologs described in the specification are partial sequences whose function has not been determined.

One of skill in the art would not recognize that Applicant was in possession of the necessary common attributes or features of the genus in view of the disclosed species. Since the disclosure fails to describe the common attributes that identify members of the genus, and because the genus is highly variant, SEQ ID NOs:1 and 4 are insufficient to describe the claimed genus.

Application/Control Number: 10/600,070 Page 9

Art Unit: 1638

Hence, Applicant has not, in fact, described Ftn2 genes or nucleic acids that hybridize to an Ftn2 gene that encodes SEQ ID NO:2, and the specification fails to provide an adequate written description of the claimed invention.

Therefore, given the lack of written description in the specification with regard to the structural and functional characteristics of the claimed compositions, it is not clear that Applicant was in possession of the claimed genus at the time this application was filed.

9. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

10. Claim 9 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter that Applicant regards as the invention. Dependent claims are included in all rejections.

Claim 9 lacks antecedent basis for the limitation "the organism".

## Claim Rejections - 35 USC § 103

11. The following is a quotation of 35 U.S.C. 103(a), which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Application/Control Number: 10/600,070

Page 10

Art Unit: 1638

12. Claim 1 is rejected under 35 U.S.C. 103(a) as being unpatentable over UniProt entry Q9FIG9 (2001, www.pir.uniprot.org/cgi-bin/upEntry?id=Q9FIG9).

The claims are drawn to a nucleic acid that hybridizes to a nucleic acid that encodes SEQ ID NO:2.

UniProt entry Q9FIG9 discloses the amino acid sequence of a protein with 99.8% identity to SEQ ID NO:2 (see search results). UniProt entry Q9FIG9 does not disclose a nucleic acid encoding the protein.

At the time the invention was made, it would have been obvious to one of ordinary skill in the art to derive a nucleic acid sequence encoding the protein taught by UniProt entry Q9FIG9. One of ordinary skill in the art would have been motivated to do so because of the established relationship in genetic code between nucleic acid and protein it encodes.

13. Claims 4-6 and 8-17 are free of the prior art, given the failure of the prior art to teach or suggest constructs comprising a nucleic acid that hybridizes to a nucleic acid that encodes SEQ ID NO:2, vectors comprising it and cells, plants and seeds transformed with it.

#### Conclusion

- 14. No claim is allowed.
- 15. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Anne R. Kubelik, whose telephone number is (571) 272-0801. The examiner can normally be reached Monday through Friday, 8:30 am - 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anne Marie Grunberg, can be reached at (571) 272-0975.

The central fax number for official correspondence is (571) 273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

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For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

Anne Kubelik, Ph.D. February 24, 2006

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                  "Structural analysis of Arabidopsis thaliana (Sequence features of the regions of 1,081,958 physically assigned P1 and TAC clones."; DNA Res. 5:379-391(1998).
                                                                                                                SEQUENCE FROM N.A.
MEDLINE=99156233; PubMed=10048488;
Assmizu E., Sato S., Kaneko T., Nakamura
                                                                                                                                                                                                       Arabidopsis thaliana (Mouse-ear cress).

Bukaryota; Viridiplantae; Streptophyta; Embryophyta; Tracheophyta;
Spermatophyta; Magnoliophyta; eudicotyledons; core eudicots; rosids;
eurosids II; Brassicales; Brassicaceae; Arabidopsis.
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A Quach H.L., Tang C., Toriumi M., Wallender E.K., Wong C., Wu H.C.,
A Yu G., Yuan S., Carminci P., Cheu H., Cheuk R., Hayashizaki Y.,
Ishida J., Jones T., Kamiya A., Kawai J., Kim C.J., Narusaka M.,
A Nguyen M., Palm C.J., Sakurai T., Satou M., Seki M., Shinn P.,
A Southwick A., Tripp M.G., Wu T., Shinozaki K., Davis R.W., Ecker J.R.
Theologis A.;
Submitted (SEP-2002) to the EMBL/GenBank/DDBJ databases.
Submitted (SEP-2002) to the EMBL/GenBank/DDBJ databases.
Submitted (SEP-2002) to the EMBL/GenBank/DDBJ databases.
ISHEL; AX091075; AAM13895.1; -.
IR EMBL; AX091075; AAM13895.1; -.
IR EMBL; AX150499; AAM13895.1; -.
IR EMBL; AX150499; AAM13997.1; 
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Query Match
Best Local Similarity
Matches 390; Conserv
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Q5_JUL_2004 (TrEMBLrel. 27,
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Plastid division protein.
Name=P0575F10.2;
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Goryza sativa nipponbare(GA3) genomic DNA, chr

Clone:P0575F10.";

Submitted (MAR-2002) to the EMBL/GenBank/DDBJ

EMBL; AP004885; EAD07942.1;

InterPro; IPR001623; DnaJ_N.

SEQUENCE 760 AA; 84134 MW; 2C44684862795B2
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Eukaryota; Viridiplantae; Streptophyta; Embryophyta; Tracheophyta;
Spermatophyta; Magnoliophyta; Lillopsida; Poales; Poaceae;
Ehrhartoideae; Oryzeae; Oryza.
MCBI_TaxID=39947;
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